US EPA
Office of Pesticide Programs

Label Review Manual
Chapter 5 – Ingredient Statement

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Chapter 5 INGREDIENT STATEMENT

I. INTRODUCTION

This chapter covers the ingredient statement and footnotes sections of the label, which must contain, as provided in 40 CFR 156.10(g), the name and percentage by weight of each active ingredient, the total percentages by weight of all “Other Ingredients" and sub statements including, but not limited to: the acid equivalent, elemental equivalent, toxic ingredients, petroleum distillates, sodium nitrite, and corrosivity.

Format

The label reviewer must review the proposed label for a clear and prominent ingredient statement that contains the name and the percentage of each active ingredient, and the total percentage of all “inert” or “other” ingredients, in the pesticide. If arsenic is present in the product, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic must be shown. 40 CFR 156.10(g)(1); PRN 97-6. The ingredient statement must be presented clearly, and be neither obscured nor crowded by surrounding text. See 40 CFR 156.10(a)(2). Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" must not be used as a heading for the ingredient statement. 40 CFR 156.10(g)(1).

II. WHAT IS INCLUDED IN AN INGREDIENT STATEMENT

A. Contents

The name and nominal concentration expressed as a percentage by weight of each pure active ingredient must be placed under the ACTIVE INGREDIENT heading and the total percentage by weight of all inert/other ingredients must be placed under the heading INERT INGREDIENT or OTHER INGREDIENT (or plural forms of these terms when appropriate).

1. **HEADINGS**. The headings "ACTIVE INGREDIENT" and “OTHER [INERT] INGREDIENT" (or plural forms of these terms when appropriate), should be the same type size, aligned to the same margin and equally prominent. PR Notice 97-6 recommends “OTHER INGREDIENT” instead of "INERT INGREDIENT,” but either may be used. Additional formatting requirements are set out at 156.10(g)(2)(ii), which provides that the “text of the ingredient statement run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.”

2. **PERCENTAGES.** The percentages shall be stated in terms of weight-to-weight and the sum of percentages of active and inert ingredients shall

be 100. Percentages shall not be expressed by a range of values as 22-25%. 40 CFR 152.10(g)(4). The percentages of active and other ingredients should be aligned by the decimal point.

B. Active Ingredient

Under 40 CFR 152.3, active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant, within the meaning of FIFRA section 2(a), except as provided in 40 CFR 174.3.

C Other Ingredient (Inert)

Under 40 CFR 152.3, inert ingredient means any substance (or group of structurally similar substances if designated by the Agency) other than an active ingredient, which is intentionally included in a pesticide product, except as provided by 40 CFR 174.3, as it relates to Plant-Incorporated Protectants. Some examples of ingredients that may be inert ingredients include: solvents, stabilizers, spreaders or stickers, preservatives, surfactants, defoamers, etc.

PR Notice 97-6 sets forth the Agency's policy concerning the use of "inert" on the label ingredients statement. Under this policy, applicants and registrants are permitted to substitute the heading "Other ingredients" for the heading "Inert ingredients."

III. LOCATION OF INGREDIENT STATEMENT

A. Front Panel

The ingredient statement is normally required to appear on the front panel of the label, preferably immediately below the product name, unless doing so is impracticable and the Agency grants permission to place it elsewhere. 40 CFR 156.10(g)(2)(i). (Refer to the sample label formats in chapter 3.) Some examples might be if the pesticide package is extremely small or irregular in shape to the point of making it difficult to place the ingredient statement on the front panel of the label. In such cases, permission may be granted, upon written request (as part of the application), for the ingredient statement to appear on the back or side panel of the label.

B. For Outside Containers/Wrappers

If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on the outside container or wrapper. 40 CFR 156.10(g)(2)(i).

IV. NAMES TO BE USED IN THE INGREDIENT STATEMENT

The label reviewer must review the names for ingredients used on the proposed label and cross-reference the names in the OPPIN database on the LAN. If none of the names are included in OPPIN, perhaps the chemical name of the active ingredient is new or the registrant used an inappropriate name. If so, check with your PM/team leader for the correct procedures to follow. Look at each section below to determine the correct names to be used in the ingredient statement.

A. Common Name

The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. 40 CFR 156.10 (g)(3). Through PR Notice 97-5, the Agency clarified what it considers as acceptable common names. EPA will permit the use of common names approved by the American National Standards Institute (ANSI) in the label ingredients statement without the accompanying scientific chemical names, and will permit the use of other common names listed in PR Notice 97-5 without the accompanying scientific chemical name. When a common name only appears on the label, EPA also recommends the inclusion on labels of Chemical Abstracts Service (CAS) numbers to identify ingredients definitively. See section C., below for further information.

The label reviewer should check OPPIN to determine the accepted common name. "(ANSI)" or a “C” in the TYPE column will be shown with the accepted common name in the Chemical Name list. An additional source for this information on older chemicals is the EPA publication, *Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels*, 4th edition (December 1979).

An alphabetical listing that contains some of the common/chemical names may also be found in the *Alphabetical Listing of Pesticide Chemicals* at the beginning of 40 CFR Part 180. Because this list only includes names for ingredients with tolerances, it is only a secondary source. Similarly, a list of some common/chemical names can be found in PR Notice 97-5.

B. Chemical Name

If the active ingredient has a common name, but not one that is considered “**accepted”** the full chemical name must be used in conjunction with a common name 40 CFR 156.10(g)(3). For example:

Acephate (0,S-dimethyl acetylphosphoramidothioate)

EPA requests that chemical names be consistent with the nomenclature used in the Chemical Abstracts (CA) Chemical Substance Index, published by the

American Chemical Society. OPPIN reflects the correct chemical name: the entry found with the "9CI" (i.e., Ninth Collective Index) designation at the end of the name. [*OPPIN tip for label reviews*: hit the Enter key on the chemical name to see the complete chemical name, which may not appear on the line if the name is too long to fit on the line.]

C. CAS (Chemical Abstracts Service) Number

The CAS number for the active ingredient(s) may be used on the label in connection with the ingredient statement. If the CAS number is used, it should appear as a sub-statement (footnote) to the ingredient statement and not in any way detract from the ingredient statement.

D. Microbial Name

If the active ingredient is a microbial agent, the Agency prefers that the microbial agent be identified by genus and species (and if appropriate also by subspecies and/or isolate number). Again, this name should be identical to the name shown in OPPIN.

E. Descriptive Name

Descriptive names approved by the Agency may be used in the ingredient statement if there is no accepted common name and no distinctive chemical name. Examples are: "Tobacco dust," "Egg solids," or "Dried blood." Approved descriptive names are listed in OPPIN, and the name shown on the proposed label must be identical to the name found in OPPIN.

F. Trademark Name

A trademark or proprietary name may not be used in the ingredient statement unless it has been accepted as a common name by the Administrator under the authority of FIFRA Section 25(c)(6). 40 CFR 156.10(g)(3).

V. CRITERIA FOR DETERMINATION OF PESTICIDAL ACTIVITY

A. Is The Ingredient Considered To Be Active?

The criteria for determination of an ingredient's active or inert status are located in 40 CFR 153.125 and PR Notice 81-4. Generally speaking an ingredient will be considered an active ingredient if, by itself, and when used as directed at the proposed use dilutions, it has the capacity to function as a pesticide or has the ability to elicit or enhance the effect of another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Ingredients such as stickers and other adjuvants which function simply to enhance or prolong the activity of an active ingredient by physical action are not generally considered to be active ingredients.

A chemical may be an active ingredient in one formulation and an inert ingredient in another. Examples are chemicals used as preservatives of a formulation, plant nutrients, or chemicals with some other non-pesticidal use.

B. Active Related Compounds

As described in PR Notice 81-4, EPA recommends that related compounds that are now distinguishable from the intended active ingredient(s) due to newer, more discriminating methods of analysis must be accounted for within the pesticide label ingredients statement. If one or more related compounds is isolated and found to have pesticidal activity to the target pest, EPA requests that it be specifically identified and quantified by percentage under the ACTIVE INGREDIENT heading of the label ingredients statement. For example:

ACTIVE INGREDIENTS:
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, α isomer.....20.0%
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, β isomer 3.0%
OTHER INGREDIENTS:..... .... 77.0%
Total 100.0%

C. Inert Related Compounds

Related compounds whose active/inert status is not determined by the registrant, must be included (without designation as related compounds or by name) under the total percentage of the INERT INGREDIENT or OTHER INGREDIENT heading (see PR Notice 81-4).

D. Equivalents:

Unless declared as an active ingredient, a related compound must not be included in expressing percent acid or metallic equivalents, nor in the declaration of "pounds active ingredient" or "acid (or metallic) equivalents per gallon" under the ingredient statement. (PR Notice 81-4).

VI. STATEMENT OF CONCENTRATIONS

A. Definition

The percent nominal concentration specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s),as that term is defined in 40 CFR 158.153(i). The nominal concentration is the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight. The nominal concentration is the only acceptable method for expressing the percentage of active ingredient in the product. **All pesticide ingredient statements must be expressed as nominal concentration.** See 40 CFR 158.155.

B. Expressions of Ingredients

1. Reviewers of proposed labels for products subject to deterioration, such as sodium hypochlorite, should note Section VIII (Deterioration), below.

2. The percent of the pure active ingredient in a technical grade product is the same as its nominal concentration. This must be indicated in Columns 10 and 13b of the CSF.

3. The nominal concentration in a formulated product is a function of the percentage by weight of the active ingredient in the product (including associated ingredients) and the purity of the source product (its nominal concentration). For example:

If the purity of the active source is 80%, as declared in column 10 of the CSF, and the percentage by weight of the active ingredient in the formulated product is 20% as indicated in column 13(b) of the CSF, the nominal concentration of the product would be 16% (20% x 0.80), consistent with the label claim. The 16% nominal concentration can be indicated between parentheses in the same column below the 20% w/w.

4. If wider limits for active and inert ingredients were justified as per the regulations 40 CFR 158.175 (c), the proposed upper and lower certified limits must be indicated on the Confidential Statement of Formula (CSF) and the guarantee of each active ingredient in percent must be indicated on the label. The guarantee ingredient statement on the label is the nominal concentration, which must be a value between the upper and lower certified limits, not equal to either value.

5. The sum of the percentage by weight of the active ingredient and intentionally added inert/other ingredients in a formulated product must equal 100%. 40 CFR 156.10(g)(4).

6. For ingredient statements which reflect the fact that the active ingredient is the only component of the product, the inert ingredients header is not necessary. For example, for a product which is 100% pure chlorine gas, the following ingredient statement is acceptable, per 40 CFR 156.10(g)(1):

ACTIVE INGREDIENT:
Chlorine.....100.0%

Assuming that the chlorine gas is only 99% pure, then the following ingredient statement would be required:

ACTIVE INGREDIENT:
Chlorine.....99.0%
OTHER INGREDIENTS..... 1.0 %

7. If the proposed label is for a liquid formulation, the label reviewer must check the Directions For Use section. If any of the use directions of the pesticide product are expressed as a certain weight of active ingredient per unit area (such as pounds per acre), a statement of the weight of the active ingredient per unit volume of the pesticide formulation must also appear at the end of the ingredient statement. 40 CFR 156.10(g)(4). This is very important when calculating the use rates. An example of this would be, "One gallon contains 4 pounds of the active ingredient (chemical)." If dosage rates in the directions for use are expressed as weight of product/unit area, the weight of the product/gallon must be stated.

VII. SUBSTATEMENTS

Based on historical practice, EPA prefers the following footnotes appear on the label, as applicable:

A. Petroleum Distillates

Products containing petroleum distillates, xylene or xylene range aromatic solvents at ≥10% should be indicated on the label immediately below the ingredient statement as a footnote below the term “Inert ingredients” or “Other Ingredients” as follows:

“Contains petroleum distillates, xylene or xylene range aromatic solvents.”

B. Ingredients of Toxicological Concern

Products containing ingredients of toxicological concern should be indicated on the label immediately below the ingredient statement as a footnote below the term “Inert Ingredients” or “Other Ingredients” as follows:

> *“This product contains the toxic ingredient (name of ingredient), at ...% (indicate the upper certified limit of the toxic component in percent).”*

C. Sodium Nitrite

Products containing sodium nitrite at >0.1% should indicate in the ingredient statement as a footnote below the term “Inert Ingredients”(or “Other Ingredients”) as follows:

> *“This product contains sodium nitrite.”*

VIII. DETERIORATION

A. Required Statement

In cases where it is determined that a pesticide formulation changes chemical composition significantly over time, the product must bear the following statement in a prominent position on the label*:*

> *"Not for sale or use after [date]."*

40 CFR 156.10(g)(6)(i). Note the product must meet all label claims up to the expiration time indicated on the label.

B. Sodium Hypochlorite.

For sodium hypochlorite products containing 5.25 - 12.5% active ingredient, the Agency historic practice has been that instead of an expiration date on the label, the following labeling statement is necessary to ensure the product is effective (because of its rapid degradation).

> *"Degrades with age and exposure to sunlight and heat. Use a test kit and increase dosage as necessary to obtain the required level of available chlorine."*

IX. SPECIFIC DESIGNATIONS FOR SOME INGREDIENT STATEMENTS

Some pesticide ingredients need specific designations on the ingredient statement for proper clarification and identification. Examples of some of these specific designations are shown below:

A. Microbial Pesticides

Biopesticides are generally subject to the same labeling provisions as conventional pesticides. They are viewed essentially the same as chemical pesticides with respect to label requirements, except for differences with the ingredient statement.

1. Viability. For products containing live microorganisms, the agency has historically required that the label indicate the equivalent number of viable units (spores, cells, colony forming units, etc.) per unit weight or volume of product. The OPPTS Harmonized Test Guidelines, Series 885 Microbial Pesticide Test Guidelines address this topic. Certified limits can be expressed as:

(a) Microbial Pest Control Agents (MPCA) units/unit weight or volume

(b) International Units of Potency per unit weight

(c) Weight percent of product

Items (a) and (b) may be expressed using biological, genetic, biochemical, serological or other appropriate data. For example:

ACTIVE INGREDIENT:
Pseudomonas syringae strain ESC-10….. 3.8% (by wt.)
OTHER INGREDIENTS: ……..96.2% (by wt.)
Total 100.0% (by wt.)

Contains at least 50 million viable cells/lb (10^5 cells/gram).

ACTIVE INGREDIENTS:
Trichoderma harzianum (ATCC 20476)* 16.6% W/W
Trichoderma polysporum (ATCC 20475)** 16.6% W/W
OTHER INGREDIENTS 66.8.% W/W
Total 100.0% W/W

* Contains a Minimum of 4.5 million colony forming units (CFU) per pound (454 grams)

** Contains a Minimum of 14 thousand colony forming units (CFU) per pound (454 grams)

2. For Bacillus thuringiensis (Bt) products, the percentage of active ingredient for the ingredient statement will be calculated using the dry weight of the fermentor solids and solubles, including the spores and toxins as the amount of the active ingredient. For liquid products, a representative sample of the technical material is to be dried down to determine the dry weight for the purpose of expressing the percentage of active ingredient on the label. The weight of the water is to be included in the inert ingredient percentage on the label. Strain variety must appear on the label. (PR Notice 72-6). The use of potency units expressed in terms of International Units (IU) per milligram of product is not allowed except when standards are obtained from an EPA-recognized international authority. Instead of International Units, company-maintained target

insect assay units are acceptable when named after the insect. (e.g. "cabbage looper units") If potency units are used, the designation should appear on the label immediately below the ingredient statement and should be followed by the statement *"the % active ingredient does not indicate product performance and potency measurements are not federally standardized.*" For example:

ACTIVE INGREDIENTS:
Bacillus thuringiensis subspecies *kurstaki* strain AB1* .5.0% w/w
OTHER INGREDIENTS: …… 95.0% w/w
Total 100.0% w/w

**Potency: 10,000 cabbage looper units per mg of product or*
4540 cabbage looper units per a pound of product

The % active ingredient does not indicate product performance and potency measurements are not federally standardized

B. Biochemical Pesticides.

The ingredients statement for a product for which the active ingredient is a naturally occurring plant regulator, (such as cytokinins, auxins, or gibberellins) and for which quantitative chemical methods and units are not available, should be stated in an acceptable and generally recognized bioassay unit. For example:

ACTIVE INGREDIENT:
Cytokinin* …… 3.0%
OTHER INGREDIENTS……..97.0%
Total 100.0%
**equivalent to 200 ppm kinetin activity*

C. Pheromone Products

The ingredient statement for pheromone dispenser labels shows the pheromone in mg. per dispenser as a footnote. This should be as reflected in the CSF.

ACTIVE INGREDIENT:
Pheromone*……...1.0%
OTHER INGREDIENTS: 99.0%
Total……100.0%
*x mg per dispenser

D. Insect Virus-based Insecticides

Pesticide products containing an insect virus as the active pesticide ingredient should indicate the number of activity units (polyhedral inclusion bodies for nuclear polyhedrosis viruses or capsules for granulosis viruses) per gram (10^6 PIBS/gm) or percentages (%). For example:

ACTIVE INGREDIENT*:
Polyhedral Inclusion Bodies of Douglas Fir
Tussock Moth Nuclear Polyhedrosis Virus. 13.5%

OTHER INGREDIENTS 86.5%
Total. 100.0%
*Contains at least 70 million activity units per gram.

Often the active ingredient statement will include "... and insect body parts..." whether the baculovirus is propagated in vivo or in vitro. For example:

ACTIVE INGREDIENTS:
Granulosis Virus of Cydia Pomonella (Coddling Moth)
(at least 5 x 108 GIBS/ml) 0.005%
OTHER INGREDIENTS: 99.995%
Insect parts/water/inert solids: 99.985%
Aureomycin (5.5%):. 0.015%
Total 100.000%

E. Salts, Amine or Ester of Acids

If the active ingredient is a salt, amine or ester of an acid, the label should declare in a substatement under the ingredient statement the percentage equivalent of the acid. For example:

ACTIVE INGREDIENTS:
Isooctyl ester of 2,4-Dichlorophenoxyacetic acid* 12.0%
Isooctyl ester of 2-(2,4-Dichlorophenoxy) propionic acid** 10.0%
OTHER INGREDIENTS:..... 78.0%
Total 100.0%
*2,4-Dichlorophenoxyacetic acid equivalent, 9.5%
**2-(2,4-Dichlorophenoxy)propionic acid equivalent, 9%

F. Copper and Zinc Salts or Complexes

Pesticide products for which the active ingredients are copper salts or complexes should declare the chemical name of the copper complex as active ingredient and the equivalent metallic copper declared in a substatement. For example:

ACTIVE INGREDIENT:
Copper naphthenate* 93.2%
OTHER INGREDIENTS:..... 6.8%
Total 100.0%
*Metallic copper equivalent, 22%

This type ingredient statement declaration is also applicable to zinc. For example, zinc naphthenate should be expressed as percent metallic zinc equivalent.

G. Brominated and/or Chlorinated Compounds

Certain brominated or chlorinated compounds may require a reference in the ingredient statement to the available chlorine or bromine. For example:

ACTIVE INGREDIENT:
1-Bromo-3-chloro-5, 5-dimethylhydantoin 86.4%
1-3dibromo-5, 5-dimethylhydantoin 8.6%
OTHER INGREDIENTS: 5.0%
Total 100.0%
Provides: 66.8% Available Bromine
25.4% Available Chlorine

H. Metal Ion Exchange Resins:

Any metal (e.g., Ag or Cu) used as pesticide, when bound to an ion exchange resin, should be declared on the label as the percent metallic equivalent with a footnote immediately below the ingredient statement specifying the identity and amount of the ion exchange resin which was used.

I. Sodium Chlorate Products:

Because sodium chlorate is extremely flammable, all pesticide products containing sodium chlorate should include a fire retardant in the formulation. These labels must bear in the vicinity of the ingredient statement, a statement indicating that the product contains a fire retardant. If the proposed label is a sodium chlorate product, check the CSF to verify that the product contains a fire retardant (column 15, Purpose in Formulation).

J. Arsenic Containing Products:

Pesticide products which contain arsenic in any form should include a substatement of the percentages of total arsenic and water-soluble arsenic calculated as elemental arsenic. See 40 CFR 156.10(g)(1). For example:

"Total arsenic, all in water soluble form, expressed as elemental' xx%"

K. Fertilizer-pesticide Combinations:

Pesticides that are formulated in combination with fertilizers bear an ingredient statement the same as any other pesticide. The fertilizer composition is shown separately from the pesticide ingredient statement and should not detract from or obscure the required pesticide labeling statements.

L. Complexing Agents:

In products containing an active ingredient bound with other agents as a complex, the active ingredient should be declared in the ingredient statement

with a footnote immediately below the active ingredient statement listing the complex formed. In the case of complexed iodine, for example, the active ingredient is titratable iodine.

ACTIVE INGREDIENT:
Iodine* ……15.0%
OTHER INGREDIENTS……..85.0%
Total 100.0%
*from (name of complexing agent)

X. INERT INGREDIENTS

Pesticide products with food use sites do not contain List 1 inerts. Reviewers need to ensure that food use products only contain inert ingredients that have a tolerance or tolerance exemption and that any limitations on the use of the inert ingredients are followed. (See 40 CFR 180 at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=47f571f55790775b2f185ea3b96ea5f1&rgn=div5&view=text&node=40:23.0.1.1.27&idno=40)

A. Special Labeling Requirements for Inerts of Toxicological Concern (List 1).

Products containing one or more other/inert ingredients on List 1 (inert ingredients of toxicological concern) have historically been required to include on the label the statement: "This product contains the toxic inert ingredient (name of inert)." See Inert Ingredients in Pesticide Products; Policy Statement OPP-36140; FRL-3190; 40 CFR 156.10(g)(7) http://www.epa.gov/opprd001/inerts/fr52.htm. This statement must be placed in close proximity to the ingredient statement in a type size comparable to other front panel text. For enforcement purposes applicants have been asked to indicate on the label the "maximum" percent of ingredients of toxicological concern characterized in the product. PR Notice 90-1, issued May 1, 1990, announced the revision and modification of previous published lists of inert ingredients in pesticide products that are of toxicological concern and require priority testing. In general, after the PR Notice was issued EPA has not register any new products containing a List 1 inert. EPA's inert list is available on the Web: Inert Ingredients in Pesticide Products | Office of Pesticide Programs | US EPA

B. Listing of Inert/Other Ingredients

Inert ingredients are not required to be identified individually in the ingredient statement except when EPA determines that such inert ingredient may pose a hazard to man or the environment. See 40 CFR 156.10(g)(7). In such a situation, EPA may require that the name of the inert be listed in the ingredient statement. However, if a registrant wants to list a particular inert ingredient in the ingredient statement, the registrant must list **all** inert ingredients directly below

the ingredient statement in descending order by weight. Only a partial listing on the label could be misleading.

Registrants are encouraged to disclose on the label the inert/other ingredients in their pesticide product either by chemical name or functional category with a brief explanatory definition. For example:

> Other Ingredients.....92.8%
> monochlorobenzene, glycerin, 8-hydroxyquinoline sulfate and dimethylpolysiloxane
>
> Other Ingredients.....92.8%
> Diluent, emulsifier, defoamer, preservatives and stabilizer

XI. ALTERNATE FORMULATIONS

EPA may approve a basic formulation and one or more alternate formulations for a single product. An alternate formulation must meet the criteria listed in 40 CFR 152.43(b)(1) through (4). The Agency may require the submission of data to determine whether the criteria have been met. Registrants are encouraged to keep their alternate formulas, if any, up-to-date. The label text of the alternate formulation product must be identical to that of the basic formulation. 40 CFR 152.43(b)(3). The Agency will not approve an alternate formulation if the alternate formulation requires a change in the label text.

The alternate formulation must have the same certified limits for each active ingredient as the basic formulation. 40 CFR 152.43(b)(1). If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation. 40 CFR 152.43(b)(2).

The analytical method required under 40 CFR 158.180 must be suitable for use on both the basic formulation and the alternate formulation.

Alternate formulas, should be clearly marked “Alternate Formula A,” “Alternate B,” etc. Further, indication that an alternate formula is replacing “alternate formula x” or is in addition to “alternate formula y” would reduce confusion.

Except for approved dye substitutions, EPA does not generally accept alternate formulations for rodenticides.